

REMARKS

This application has been amended and is believed to place it in condition for allowance at the time of the next Official Action.

Objections

Claim 33 was objected to because "Claim 33 (line 33) is grammatically incorrect, and should recite '...information that is characteristic...'".

As to claim 33, the objected-to recitation was previously amended to "information that are characteristic". Therefore, no further amendment is believed necessary.

Claim 41 was objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 41 has been amended to depend from claim 37.

Withdrawal of the claim rejection is solicited.

Claim Rejections - 35 USC § 101

Claims 36-42 stand rejected under 35 U.S.C. 101 as being drawn to non-statutory subject matter. The Official Action states that:

i) these claims are rejected are drawn to a method for managing batches of cells collected from humans or animal subjects for their deferred use;

ii) a claimed process is statutory under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus of statutory subject matter under 35 U.S.c. §101 (i.e. a machine, manufacture, or composition of matter), or (2) it transforms a particular article into a different state or thing;

iii) regarding the required tie to a particular machine or apparatus, the process required by claims 36-42 are not limited to a particular apparatus or machine, as the claims do not recite any specific machines for carrying out these steps; and

iv) to qualify as a statutory process, the claims should require use of a machine within the steps of the claimed subject matter or require transformation of an article to a different state or thing.

The Official Action further states that insignificant data gathering or post-solution activity (e.g. extracting and processing cells, conditioning and preserving cells) in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter; and that the applicants may overcome the rejection by amendment of the claims to perform critical steps of the claimed invention using a

specific computer, device, or processor having structure (cautioning against introduction of new matter in an amendment).

Response to § 101 Rejection

Without acknowledging the rejection is proper, applicant has amended claim 36 to recite storing the collected cells, in a storage device for conditioning and preserving the collected cells, into one or more storage centers (see claim 33).

Applicant has also amended claim 36 to recite that the personal database is stored within a physical medium accessible by a computer system and that the expert system is executed within the computer system (See Figure 2, published paragraphs [0085], [0091-0093], [0095], for example). Such could be located within a management center controlling the plurality of storage sites and one or more preparation and cryo-preservation centers (now recited in new claim 43, which reads on the elected species of Group I).

No new matter is entered by these amendments.

As the claims have been amended consistent with the guidance given by the Examiner and to recite the invention in compliance with section 101, withdrawal of the rejection is solicited.

Claim rejections - 35 USC § 112, 2nd Paragraph

Claims 33-42 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention.

The Official Action stated that claim 33 (5th line from the last) recites "optimal proportions of various selected types of cells." The Official Action stated that the term "optimal proportions" implies that proportions of cells are chosen by some existing criteria, and that the specification does not provide a standard or criteria for optimal proportions such that one of ordinary skill in the art would know the metes and bounds of optimal proportions, as claimed. Further, the Official Action stated that the term "optimal proportions" is a relative term which renders the claim indefinite.

Without acknowledging that the rejection is proper, the claim has been amended to recite "- determining parameters of said deferred-use protocol, using data stored in said database, said determined parameters including optimized proportions of various selected types of cells among cells stored in said personal cell library,...". Even if the specification does not teach what would be an optimal proportion, it is within the skill of the art to optimize proportions. This amendment adds no new matter and brings the claim within section 112, second paragraph. Withdrawal of the rejection is solicited.

Claim Rejections - 35 USC § 103

I. Claims 33, 36, 37, 38, 39, 41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lefesvre et al. (W0/19991053030; Publication Date: 10/21/1999, p.1-5; English translation version), in view of Barnhill et al. (US 6,248,063; Filed Dec. 22, 1997), and in view of Shortliffe et al., (In Proc. Seventh International Joint Conference on Artificial Intelligence, 1981, Vol. 60, pp. 876-881; IDS filed 09/12/2006).

II. Claims 33-34 and 36-41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lefesvre et al. (W0/19991053030; Publication Date: 10/21/1999, p.1-5; English translation version), in view of Barnhill et al. (US 6,248,063; Filed Dec. 22, 1997), and in view of Shortliffe et al., (In Proc. Seventh International Joint Conference on Artificial Intelligence, 1981, Vol. 60, pp. 876-881), and further in view of Zanin et al. (W0/1997/045056; Publication Date: 12/4/1997) and Cha et al. (Physiol. Meas., 1994, Vol. 15, p. 129-137).

III. Claims 33, 34, and 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lefesvre et al. (W0/19991053030; Publication Date: 10/21/1999, p.1-5; English translation version), in view of Barnhill et al. (US 6,248,063; Filed Dec. 22, 1997), in view of Shortliffe et al., (In Proc. Seventh International Application/Control Number: 10/687,636 Joint Conference on Artificial Intelligence, 1981, Vol. 60, pp. 876-881), in View of Zanin et al. (W0I1997/04S0S6; Publication

Date: 12/411997), in view of Cha et al. (Physiol. Meas., 1994, Vol. 15, p. 129-137), and further in view of **Tomoyasu** (Applied And Environmental Microbiology, Jan. 1998, p.376-382).

Traverse

In summary, the claims are being rejected as obvious over Lefesvre (WO 99/53030 A) in view of Shortliffe et al., Barnhill et al. and further in view of WO 97/045056 and still further in view of the article Cha et al. or even in view of the article by Tomoyasu.

The primary reference **Lefesvre** teaches a method to manage batches of immunocompetent cells for deferred use. This **Lefesvre** method comprises steps for:

- conditioning and storing batches of immunocompetent cells in one or several storing cryogenic sites,
- constituting a personal library of immunocompetent cells using said batches, said personal cell library containing a sum of immunity information stored in the membranes of the collected immunocompetent cells from one or more of said batches of immunocompetent cells, and

for a reuse of the plural batches by the subject, on request from a cell treatment center where the subject is to reuse one of the plural batches,

- interrogating the management data base at the center for management to localize one of the plural batches at one of the cryogenic storage sites; and

- transferring the one of the plural batches from the one of the cryogenic storage sites to the requesting cell treatment center as directed by the center for management.

The Official Action states that Lefesvre does not teach:

**I.** an expert system wherein information is entered in the form of biological items to which a set of rules stored in a knowledge base is applied,

**II.** implementing into said expert system a process for determining a deferred-use protocol comprising biological and technical indications required for cell processing before re-use of a batch of immunocompetent cells; and

**III.** a processor for processing identity data to determine parameters of a deferred-use protocol.

**A. Shortliffe et al. does not teach III** (a processor for processing identity data to determine parameters of a deferred-use protocol).

The Official Action states that Shortliffe teaches an expert system for clinical protocol management.

The Official Action further states that Shortliffe teaches **III** (a processor for processing identity data to determine parameters of a deferred-use protocol) as the expert

system of Shortliffe shows parameters relevant for deferred use protocols on p877 col 2 \$2, p878 col. 2 \$4 and p879 col.1, col2, Advice.

Applicant respectfully disagrees for the following reasons.

On page 877 col 2, \$2 Shortliffe teaches that the Reasoner uses initial data about the patient diagnosis, data about previous treatment, results of current laboratory tests plus the protocol-specific information in its knowledge base to generate recommendation.

There is no teaching about the parameters of a deferred-use in Shortliffe on page 877 col. 2, \$2.

Moreover, on page 878 col 2, \$4 Shortliffe gives a definition of the word "Parameters" used in Shortliffe: "Parameters represent the attributes of patients, drugs, tests etc. that are relevant for the protocol management task. Each piece of information accumulated during a consultation is represented as the value of a parameter".

Shortliffe then describes how to determine the value of a parameter.

The word "Parameters" in Shortliffe doesn't designate the parameters of a deferred-use protocol.

Rather, the word "parameters" designates the information entered in the expert system, i.e. "each piece of information accumulated during a consultation". This meaning of



the word "parameters" is confirmed on page 878, col 2, \$2 where it is stated that "Knowledge in oncology domain is represented using four main types of data structure: Contexte, **Parameters**, Rules and Control Blocks.

In making this rejection, the Official Action has not properly interpreted the recitation concerning "parameters" and rather it seems that the Official Action has been confused by the word "parameters" used in Shortliffe.

**B. It is not obvious to combine Lefesvre with Shortliffe et al.**

The Official Action states that it would have been obvious for a person having ordinary skill in the art at the time of the instant invention to modify Lefesvre to take into account the teaching of Shortliffe.

Applicant respectfully disagrees.

Indeed, in his Official Action the Examiner states that "the factual inquiries...for determining obviousness under 35 U.S.C. 103(a)" comprise "4.Considering objective evidence present in the application indicating obviousness or non obviousness".

But in this argument, the Official Action doesn't mention any objective evidence that "the system described in this report has relied on the efforts of several physicians and computer scientists". This statement is objective evidence that the modification of Lefesvre to take into account the teaching of Shortliffe is not obvious as the system of Shortliffe

necessitated the efforts of **ten** physicians and computer scientists.

Moreover, Shortliffe deals with determining an optimal treatment among several treatments whereas Lefesvre deals with immunocompetent cell management. Shortliffe doesn't mention any deferred-use of any type of cell and doesn't mention that the described system may be used for such a cell management. There is no objective evidence that a person having ordinary skill in the art would combine Shortliffe with Lefesvre.

**C. It is not obvious to combine Lefesvre with Shortliffe et al. and Barnhill et al. to reach to the claimed invention**

The Official Action states that, at the time of the instant invention, it would have been obvious for a person having ordinary skill in the art (PHOSITA) to modify Lefesvre in view of Shortliffe and Barhill to reach to the invention as claimed in claim 33.

Applicant respectfully disagrees.

There is no information in Lefesvre that would constitute a motivation for the PHOSITA to combine the teaching of Lefesvre with the teaching of Barnhill or the teaching of Shortliffe. Neither of Barnhill and Shortliffe deals with the specific domain of Lefesvre, i.e., cell management for deferred-use.

The Official Action doesn't state objective evidence that would lead the PHOSITA to identify and to combine a specific part of Shortliffe and a specific part of Barnhill with Lefesvre.

It therefore appears that the Official Action realizes reasoning a *posteriori*. It is respectfully pointed out that the obviousness reasoning shouldn't be inductive reasoning from the differences of what what references teaches how that reference is different from the claimed invention.

The Official Action does not follow the direction of *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18, which set an objective analysis for applying section 103: "[T]he scope and content of the prior art are ... determined; differences between the prior art and the claims at issue are ... ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined."

The present rejections merely apply hindsight. Such an approach is not permitted.

The Federal Circuit emphasized in July, 1998 that "[m]ost, if not all, inventions are combinations and mostly of old elements." In *re Rouffett*, 47 USPQ 2d 1453, 1457 citing to *Richdel, Inc. v. Sunspool Corp.*, 219 USPQ 8, 12 (Fed. Cir. 1983). The Federal Circuit continued by noting that "rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a

blue print for piecing together elements in the prior art to defeat the patentability of the claimed invention." Thus, in order to prevent the use of such hindsight, the Official Action must show reasons that the skilled artisan, with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. The present rejection fails to meet this requirement.

For all these reasons claims 33 and 36 are not obvious for a person having ordinary skill in the art, taking into account the fair teaches and suggestions of Lefesvre, Barnhill et al. and Shortliffe et al. The references not specifically discussed do not cure these defects.

The dependant claims are non-obvious at least for depending from an non-obvious claim.

D. Furthermore, applicant respectfully notes that the present application (10/687,636) has been filed on October 20, 2003 as a Continuation-In-Part of an application No. 09/685,961 filed on October 16, 2000 and claiming a priority of January 21, 2000, thus less than one year and a half after the filing date (July 20, 1998) of US patent 6,415,201 (Lefesvre) co-owned by the present Applicant.

The purpose of this new patent application was indeed to seek a protection for a major improvement of the patented method and system for management of batches of cells, consisting in providing an expert system wherein information is entered in

the form of biological items to which a set of rules stored in a knowledge base is applied, and implementing into said expert system a process for determining a deferred-use protocol comprising biological and technical indications required for cell processing before re-use of a batch of immunocompetent cells.

At the date of the invention subject of US patent 6,415,201 (Lefesvre), it would not have been obvious to propose such an improvement since the main concern was essentially to process the stored immunocompetent cells identified for a deferred use, merely on the basis of the concerned person's present status. For such a pre-use process, it was not necessary to implement an expert system nor a knowledge base since the deferred -use protocol was clearly basically limited to health safety and cell integrity control.

On the contrary, in the present invention, the aim is to determine a deferred-use protocol based on a cumulative knowledge of the collected health-status data along a given - generally long - time period. Therefore, this characterizing approach, which has been acknowledged by the Examiner as novel over Lefesvre, is also non-obvious over the prior art.

Reconsideration and allowance of all claims are respectfully requested

Reconsideration and allowance of all the claims are respectfully requested.

In view of the foregoing Remarks, therefore, applicant believes that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/Roland E. Long, Jr./  
Roland E. Long, Jr., Reg. No. 41,949  
209 Madison Street  
Suite 500  
Alexandria, VA 22314  
Telephone (703) 521-2297  
Telefax (703) 685-0573  
(703) 979-4709

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